

Remarks/Arguments

Claims 18 and 19 have been amended in view of the rejection under 35 USC § 112, 2nd paragraph with regard to (c-2) and (c-4). In addition, claim 22 was amended an attempt to overcome the rejection under 35 USC § 112, 1st paragraph. Support for this amendment can be found throughout the entire specification at, for example, pages 30-31. It is submitted that no new matter has been added by the above amendments.

The Applicants acknowledge with appreciation that the previous rejections under 35 USC § 112, 2nd paragraph, and 35 USC § 103 were withdrawn.

Indefiniteness Rejection

A. Claims 18-19 were rejected under 35 USC § 112, second paragraph. (Office Action at page 3.) In making the rejection, the Patent Office asserted that there is insufficient antecedent basis in claim 18 for (c-2) and (c-4). (*Id.*)

For the reasons set forth below, the rejection is traversed.

Claim 18 has been amended to remove reference to (c-2) and (c-4). In view of those amendments, it is submitted that the instant rejection is moot and withdrawal thereof is respectfully requested.

B. The Patent Office asserted that claims 18 and 19 “contain[] a broad and a narrow limitation in the same claim.” (Office Action at page 3.) Specifically, the Patent Office appears to take issue with the fact that claims 18 and 19 “state that R³ is a group of formula (b-1) and then recites limitations for the formula in the same claim, which is the narrower statement of the range/limitation.” (*Id.*)

It is submitted that the amendments to claims 18 and 19 further clarify the claimed subject matter in an attempt to address the Patent Office’s concerns. It is believed that the instant rejection is moot and should be withdrawn.

Enablement Rejection

Claim 22 stands rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. (Office Action at page 7.)

The Applicants respectfully traverse this rejection.

The Patent Office focused its analysis on, among other things, the language used in the claim concerning chemotherapeutic agents:

This is only a fraction of compounds that may be considered "chemotherapeutic agents".

(Office Action at pages 8-9.)

The Patent Office concluded that:

burdensome. One skilled in the art could not take the information provided in the disclosure to make and use the claimed compositions. One of ordinary skill would not expect every possible chemotherapeutic agent in combination with the compounds of the present invention to work perfectly in a synergistic manner to afford potent therapeutic agents. Therefore undue experimentation would be expected.

(Office Action at page 10.)

Claim 22 has been amended to list specific chemotherapeutic agents in an attempt to address the Patent Office's concerns concerning the number of chemotherapeutic agents included in claim 22. The applicant does not acquiesce to the position forwarded by the Patent Office, rather claim 22 has been amended solely to expedite prosecution on the merits. The subject matter that was removed from claim 22 may be re-introduced in this or any other patent application claiming the benefit of priority to the captioned patent application.

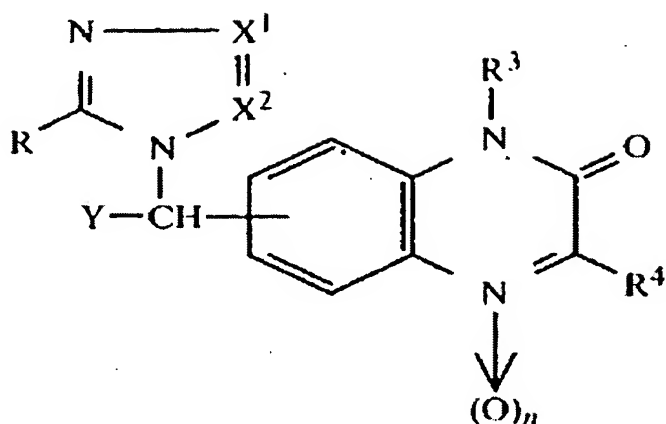
It is believed that the current amendment to claim 22 overcomes the instant rejection and withdrawal thereof is respectfully requested.

Obviousness Rejection

Claims 17, 18, and 21 were rejected under 35 USC §103(a) as being unpatentable over US Pat. No. 5,028,806 ("Venet"). (Office Action at page 6.)

For the reasons set forth below the rejection, respectfully is traversed.

Venet discloses

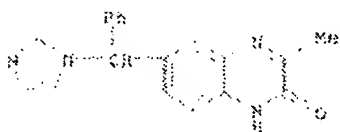


(Venet at Table 9.)

In particular, compound 57 of Table 9 has the following substituents: R is H; -
 $X^1=X^2$ is $-\text{CH}=\text{CH}-$; Y is C_6H_5 ; P=6, R^3 : H; R^4 : CH_3 , and n : 0.

In making the rejection, the Examiner asserted that

Venet teaches the following compound:



wherein R_1 = methyl, n = 0, X = N, R^2 = H, R^3 = imidazolyl, and $\text{R}^{4-6,12}$ = H (see
col.43, compound 57 in table 9).

(Office Action at page 6.) The Patent Office acknowledged, however, that Venet differs
from the presently claimed invention “is the substituent R^3 (imidazolyl v. pyrazolyl).”

(Office Action at page 7.)

To fill the acknowledged gap, the Patent Office relied upon the conclusion that
“the two compounds are just regioisomers.” (*Id.* Emphasis added.) The Patent Office
also relied on MPEP 2144.09 concerning positional isomers.

The Patent Office then concluded that applicants are “taking a well-known
compound....and doing a simple modification to the molecule (atom flipping on the
heterocyclic ring) and the claims are obvious over the prior art. (*Id.*)

As is fundamental, a *prima facie* case of obviousness must be based on facts, “cold hard facts.” When the rejection is not supported by facts, it cannot stand.

It is noted that the Patent Office used the term “regioisomers” when comparing a single compound encompassed by the instant claims and compound 57 in Venet. Such terminology is confusing as it is understood that a regioisomer refers to a compound produced as a result of the different outcomes of chemical reactions in which there are different orientations or sites to choose from. It is not seen where the facts have been presented by the Patent Office to support such a conclusion concerning whether the two compounds compared are regioisomers. For this reason, the rejection is improper and should be withdrawn.

After setting forth the conclusion that the compared compounds are regioisomers, the Patent Office then relies on a passage from the MPEP concerning positional isomers to support its rejection. It is not seen how the views expressed concerning positional isomers has any bearing on regioisomers and vice versa. Further Venet describes imidazole and triazole containing compounds. There is no suggestion or disclosure of pyrazole in Venet nor, given the “unpredictability” (*see* Office Action at page 9) in this area it is not seen where there is any expectation of success. For this reason, the rejection is not proper and should be withdrawn.

Obviousness-type Double Patenting

A. Claims 17-22 also have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4, 6, 12, 14-16, and 26-30 of co-pending application number 10/595,882. (Office Action at pages 4-5.) The Office Action did not indicate that the rejected claims are otherwise allowable. Upon notification in the Office Action that claims 17-22 are allowable but for this rejection, the substance of this rejection will be addressed.

Finally, the Examiner is invited to call the applicants’ undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP

§ 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Accordingly, entry of the claims and allowance of the claims is respectfully requested.

Respectfully submitted,

By: /Timothy E. Tracy/
Timothy E. Tracy
Reg. No. 39,401

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
(732) 524-6586
Dated: March 30, 2009
Customer No. 000027777